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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,039	09/22/2005	Clifford J. Steer	P0093AUTL00	8552

79384 7590 03/31/2009

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EXAMINER	
CLARK, SARA E	

ART UNIT	PAPER NUMBER
4121	

MAIL DATE	DELIVERY MODE
03/31/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,039	STEER ET AL.	
	Examiner	Art Unit	
	SARA E. CLARK	4121	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/7/2006, 6/2/2006, 6/9/2008, 12/9/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is a 35 U.S.C. 371 (national stage) application of PCT/US03/31989, filed 10/8/2003, which claims benefit of priority to provisional applications 60/425,210, filed 11/7/2002, and 60/451,615, filed 3/3/2003. Claims 1-17 are pending.

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The instant claims are supported by the disclosure of provisional applications 60/425,210, filed 11/7/2002, and 60/451,615, filed 3/3/2003, and are thus entitled to an effective filing date of 11/7/2002.

Information Disclosure Statement

2. The information disclosure statements (IDS) submitted on 4/7/2006, 6/2/2006, 6/9/2008, and 12/9/2008 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Steer et al. (WO99/15179, published 4/1/1999, provided by Applicants on the IDS dated 4/7/2006).

WO99/15179 teaches the administration of an effective amount of an apoptosis-limiting compound, specifically, a hydrophilic bile acid such as ursodeoxycholic acid or salts or analogs thereof, or a combination thereof, to a human patient (p. 3, lines 16-22) to treat cerebrovascular disease, including stroke and stroke injuries, in which neurons die from apoptosis (p. 4, lines 8-13; p. 16, lines 22-30).

The instant specification distinguishes two types of strokes by their etiology, hemorrhagic and ischemic, but affirms that neuronal apoptosis results from both types (p. 6, lines 11-18; p. 15, line 29 to p. 17, line 17), and that apoptosis is the underlying mechanism to be treated by ursodeoxycholic acid and its salts or analogs (p. 21, lines 21-22; p. 22, lines 24-26), a point reinforced by reference to the claimed compounds as "apoptosis-limiting compounds" (p. 8, lines 1-2), just as in WO99/15179. Therefore, the compounds, methods, and scope of "stroke" and "stroke injuries" taught by WO99/15179 reads on claims 1, 2, 6-9, 13, and 14.

Alternatively, it is submitted that the limitation "for treating a patient having a nervous system injury" in the preamble of claims 1 and 8 should not be afforded any patentable weight. Although no litmus test defines when a preamble limits claim scope (see *Corning Glass Works v. Sumitomo Electric U.S.A., Inc.*, 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989)), some guideposts have, nevertheless, emerged from various cases discussing the preamble's effect on claim scope. For example,

dependence on a particular disputed preamble phrase for antecedent basis may limit claim scope because it indicates a reliance on both the preamble and claim body to define the claimed invention. *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995) ("[W] hen the claim drafter chooses to use both the preamble and the body to define the subject matter of the claimed invention, the invention so defined, and not some other, is the one the patent protects."). Here, claims 1 and 8 recite administering a drug to "a patient" rather than "the patient" set forth in the preamble. Stated differently, claim 1 does NOT read, "A method of treating a patient having a nervous system injury, the method comprising administering to the patient … .". Consequently, it can be readily seen that the claimed act for administering a compound to a patient does not "rely on" (i.e., refer back to) the preamble and, as such, is not further limited by it. That is, in contrast to *Bell Communications*, Applicants' preamble does not recite any essential structure or steps that are "necessary to give life, meaning, and vitality" to the claim. See *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999).

In addition, the language denoting administration to "*a* patient" rather than "*the* patient" disconnects the patentable step of administering a drug from additional portions of the claim setting forth further intended use of that step; namely, the follow-on "wherein clause" in the body of the claim. Consequently, the "wherein clause" has not been afforded any patentable weight either. That is, the "wherein the nervous system injury is associated with hemorrhage" amounts to mere intended use language that fails to limit the scope of the claims. See MPEP 2111.04.

WO99/15179 also teaches the administration of ursodeoxycholic acid and its salts or analogs in combination with a pharmaceutically acceptable carrier, by parenteral or oral routes (p. 5, lines 8-11), which reads on claims 3-5 and 10-12. Finally, Steer et al. teach that examples of analogs of hydrophilic bile acids include conjugated derivatives of ursodeoxycholic acid, and that two particularly preferred conjugated derivatives are tauro-ursodeoxycholic acid and glyco-ursodeoxycholic acid (p. 12, lines 12-15), which reads on claims 15-17.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Given the interpretation of the preamble discussed above, claims 1, 3-5, 8, and 10-12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8-11 of U.S. Patent No. 6,544,972. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

a. Examined claims 1 and 8, drawn to a method of administering to a patient an effective amount of a hydrophilic bile acid, are generic to and anticipated by the species recited by reference claim 8, drawn to a method of administering to a patient an effective amount of ursodeoxycholic acid.

b. For the same reason, examined claims 3 and 10 are anticipated by reference claim 9, both of which recite the additional limitation that the compound is administered in combination with a pharmaceutically acceptable carrier.

c. For the same reason, examined claims 4 and 11 are anticipated by reference claim 10, both of which recite the additional limitation that the compound is administered parenterally.

d. For the same reason, examined claims 5 and 12 are anticipated by reference claim 11, both of which recite the additional limitation that the compound is administered orally.

It is clear that all the elements of examined claims 1, 3-5, 9, and 10-12 are to be found in reference claims 8-11 as the examined claims fully encompass the reference claims as described above. Thus, the inventions of reference claims 8-11 are in effect species of the generic inventions of examined claims 1, 3-5, 9, and 10-12. It has been held that the generic invention is anticipated by the species. See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since examined claims 1, 3-5, 9, and 10-12 are anticipated by reference claims 8-11, they are not patentably distinct.

7. Given the interpretation of the preamble discussed above, claims 1 and 8 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 30 of copending Application No. 10/246,025. Although the conflicting claims are not identical, they are not patentably distinct from each other because reference claim 30 is drawn to a species (a method of treating a patient having a neurodegenerative disease by administering tauro-, glyco- or ursodeoxycholic acid) which anticipates the genus encompassed by examined claim 1 (a method of treating a patient by administering a hydrophilic bile acid), and the genus encompassed by

examined claim 8 (a method of treating a patient by administering tauro-, glyco- or ursodeoxycholic acid).

For the same reasons, examined claims 2 and 9 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over reference claim 36, drawn to a species (with the further limitation that the patient is a human patient) which anticipates the genus encompassed by examined claims 2 and 9 (also further limited in that the patient is a human patient).

Similarly, examined claims 3 and 10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over reference claim 31, drawn to a species (with the further limitation that the compound is administered with a pharmaceutically acceptable carrier) which anticipates the genus encompassed by examined claims 3 and 10 (also further limited in that the compound is administered with a pharmaceutically acceptable carrier).

In addition, examined claims 4 and 11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over reference claim 32, drawn to a species (with the further limitation that the compound is administered parenterally) which anticipates the genus encompassed by examined claims 4 and 11 (also further limited in that the compound is administered parenterally).

Further, examined claims 5 and 12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over reference claim 33, drawn to a species (with the further limitation that the compound is

administered orally) which anticipates the genus encompassed by examined claims 5 and 12 (also further limited in that the compound is administered orally).

Finally, examined claim 15 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over reference claim 34 (reciting glycoursodeoxycholic acid) which anticipates examined claim 15 (also reciting glycoursodeoxycholic acid). Likewise, examined claim 16 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over reference claim 35 (reciting tauroursodeoxycholic acid) which anticipates examined claim 15 (also reciting tauroursodeoxycholic acid).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

7. Claims 1-17 are rejected.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARA E. CLARK whose telephone number is (571) 270-7672. The examiner can normally be reached on Mon - Thu, 7:30 am - 5:00 pm (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patrick J. Nolan can be reached on 571-272-0847. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SEC

/Patrick J. Nolan/
Supervisory Patent Examiner, Art Unit 4121